

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

STERIGENICS U.S., LLC,
a Delaware limited liability company,

Plaintiff,

v.

JOHN KIM, not individually, but solely in his
capacity as Acting Director of the Illinois
Environmental Protection Agency, and the
ILLINOIS ENVIRONMENTAL PROTECTION
AGENCY,

Defendants.

No. 19-cv-01219
Hon. Matthew Kennelly

**DEFENDANT'S RESPONSE IN OPPOSITION
TO EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER,
PRELIMINARY INJUNCTION, AND PERMANENT INJUNCTION**

EXHIBIT A

JOHN KIM

DECLARATION OF JOHN J. KIM

I, John J. Kim, declare as follows:

1. Since January 21, 2019, I have been employed as the Acting Director of the Illinois Environmental Protection Agency (the “Illinois EPA” or “Agency”). In that capacity, I have ultimate decision-making authority for the Agency; develop and oversee administration of policy and operations of the Agency; interact with public, legislature, regulated community, elected officials and environmental interest groups; work with Governor’s Office to implement policies and initiatives of the Governor; and provide feedback and guidance on environmental issues in Illinois.

2. I previously served in a similar position as Director/Interim Director of the Agency between October 2011 and March 2013.

3. Prior to being appointed the Acting Director of the Illinois EPA, I served as the Chief Legal Counsel, Ethics Officer for the Agency from May 2009 to October 2011, and from March 2013 to January 2019. In that capacity, I provided representation to the Director and staff on all legal matters, including statutory and regulatory interpretation and implementation, policy decisions and personnel issues; interacted with the Office of the Illinois Attorney General, United States Environmental Protection Agency (“USEPA”), regulated community, legislature, elected officials and environmental interest groups; supervised attorneys and support staff totaling approximately 40 employees; and served as legal liaison with Governor’s Office.

4. On February 15, 2019, I, in my capacity as the Acting Director of the Agency, signed the Seal Order in the matter of *Commercial Sterilization Operations at 7775 South Quincy Street and 830 Midway Street, Willowbrook, DuPage County, Illinois* against Sterigenics U.S., LLC, a true and correct copy of which is attached hereto as Exhibit 1 (the “Seal Order”).

5. The effect of the Seal Order was to seal all storage containers of ethylene oxide at Sterigenics' facility located at 7775 South Quincy Street and 830 Midway Street, Willowbrook, DuPage County, Illinois (collectively, the "Facility"), thereby preventing the commencement of any new sterilization cycles and thus any resulting ethylene oxide emissions from the Facility.

6. Ethylene oxide is a hazardous air pollutant under Section 112(b)(1) of the Clean Air Act, 42 U.S.C. 7412(b)(1).

7. In its decision-making process regarding the issuance of the Seal Order, the Illinois EPA relied upon the Public Health Consultation Letter that the United States Department of Health and Human Services' Agency for Toxic Substances and Disease Registry ("ATSDR") issued on August 21, 2018 (the "Consultation Letter"). A true and correct copy of the Consultation Letter is attached hereto as Exhibit 2.

8. In that Consultation Letter, the ATSDR concluded, in part, that:

It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO [ethylene oxide] concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:

- 1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* (emphasis in original) for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated cancer risks *present a public health hazard to these populations*. (emphasis in original).

(Exhibit 2.)

9. The ATSDR relied upon the "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" that the USEPA's Integrated Risk Information System ("IRIS") program released in December 2016 ("2016 IRIS Evaluation"). (*Id.*) The 2016 IRIS Evaluation, among other things,

- a. recharacterized ethylene oxide as from “probably carcinogenic to humans” to “carcinogenic to humans,” or a known human carcinogen;
- b. increased the lifetime inhalation cancer unit risk estimate for ethylene oxide about 30 times;
- c. recognized that an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers at sterilization operations using ethylene oxide, and
- d. recognized that there is sufficient evidence to establish a causal relationship between ethylene oxide exposure and breast cancer in women.

(*Id.*)

10. The ATSDR used the highest [then-available] residential area and commercial area sampling results (2.1 micrograms per meter³ and 9.1 micrograms per meter³, respectively) to reach its conclusion. (*Id.*)

11. In its decision-making process regarding the issuance of the Seal Order, the Illinois EPA also relied upon (a) the USEPA’s results of sampling that it conducted in November and December 2018, a true and correct copy of which is attached hereto as Exhibit 3 (the “USEPA Results”), and (ii) the Village of Willowbrook’s (“Village’s”) results of sampling that it conducted in February 5-8, 2019 (the “February 5-8 Results”), a true and correct copy of which is attached to the Affidavit of Dyron Hamlin, MS, PE, CIH (“Hamlin Affidavit”) filed contemporaneously herewith.

12. The USEPA Results included multiple instances whereby such results were substantially higher than the highest applicable residential and commercial results that ATSDR utilized in reaching its conclusions that “an elevated cancer risk exists (emphasis in original) for

residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated cancer risks present a public health hazard to these populations.” (Exhibit 2.)

13. The higher results were particularly troubling given that in July 2018, Sterigenics completed a construction project to duct the emissions of ethylene oxide from the backvent valves of Sterigenics’ sterilization chambers to existing scrubbers, which Sterigenics told the Illinois EPA would result in lower ethylene oxide emissions from its Facility.

14. On February 14, 2019, the Illinois EPA received a copy of the February 5-8 Results. The measured airborne concentration of ethylene oxide at the Willowbrook Police Department – Outdoors location and the Willowbrook Village Hall-Outdoors location were 160 micrograms per meter³ and 38 micrograms per meter³, respectively. These numbers were several times higher than the ATSDR and the previous highest sampling results.

15. As a result of the Village’s February 5-8 Results, the Agency found that an imminent and substantial endangerment to public health existed. Specifically, (a) ethylene oxide is a known human carcinogen; (b) there was no significant source of ethylene oxide, other than Sterigenics, that could be contributing to the higher ethylene oxide concentrations; (c) the ATSDR had concluded, based upon 2.1 micrograms per meter³ for residential areas and 9.1 micrograms per meter³, that “an elevated cancer risk exists” and “[t]hese elevated cancer risks present a public health hazard” to the residents and workers exposed to the elevated airborne ethylene oxide concentrations (Exhibit 2); (d) the outdoor concentrations of ethylene oxide, a known human carcinogen, at the Willowbrook Police Department and Willowbrook Village Hall were substantially higher than the ATSDR and prior sampling results; and (e) the USEPA had identified

7 census tracts near Sterigenics' operations as having cancer risk scores greater than 1 in 10,000 (*ie.*, an additional 1 incidence of cancer per 10,000 people) (Exhibit 1 at p. 2.).

16. The Illinois EPA has a duty to protect human health and the environment.

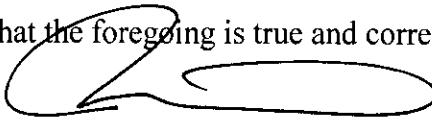
17. Section 34 of the Illinois Environmental Protection Act, 415 ILCS 5/34 (the "Act"), is the only provision of the Act, whereby the Illinois EPA could take immediate action to protect the public health.

18. The Seal Order should be rescinded only when measures are in place to prevent emissions of ethylene oxide that contribute to ambient levels of ethylene oxide which present a public health hazard to residents and off-site workers in the Willowbrook community.

19. On February 19, 2019, I received a copy of results from the Village's sampling conducted on February 11-14, 2019, a true and correct copy of which has been filed contemporaneously herewith.

20. Given the extremely high measured airborne concentration of ethylene oxide at the Willowbrook Police Department – Outdoors location of 320 micrograms per meter³, the Seal Order should not be rescinded.

I declare under penalty of perjury that the foregoing is true and correct.



John J. Kim, Acting Director
Environmental Protection Agency of
the State of Illinois

Executed on February 20, 2019.

EXHIBIT 1

ENVIRONMENTAL PROTECTION AGENCY
OF THE STATE OF ILLINOIS

IN THE MATTER OF:

Commercial Sterilization Operations
at 7775 South Quincy Street and
830 Midway Street, Willowbrook,
DuPage County, Illinois

SO: 2019-

RESPONDENT:

Sterigenics U.S., LLC

SEAL ORDER

This matter comes before the Acting Director of the Illinois Environmental Protection Agency, John J. Kim, pursuant to Section 34(b) of the Illinois Environmental Protection Act, 415 ILCS 5/34(b) (2018), for a Seal Order in this matter.

THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY HEREBY FINDS THAT:

1. There exist two buildings located in close proximity in the Village of Willowbrook, DuPage County, Illinois - one at 7775 South Quincy Street and the other at 830 Midway Street. Both buildings house commercial sterilization operations and associated storage and transshipment activities.
2. The owner of both buildings, and the operator of the commercial sterilization operations, is Respondent, Sterigenics U.S., LLC.
3. Respondent uses ethylene oxide in its sterilization operations, and ethylene oxide is released from Respondent's buildings to the atmosphere.
4. In 1990, the United States Environmental Protection Agency listed ethylene oxide as a hazardous air pollutant under Section 112(b)(1) of the Clean Air Act, 42 U.S.C. 7412(b)(1).
5. From 1985 to 2016, the United States Environmental Protection Agency categorized ethylene oxide as "probably carcinogenic to humans."
6. In December 2016, the United States Environmental Protection Agency's Integrated Risk Information System ("IRIS") program released an "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" ("2016 IRIS Evaluation"), which recharacterized ethylene oxide as "carcinogenic to humans" while increasing the lifetime inhalation cancer unit risk estimate for ethylene oxide about 30 times.
7. In the 2016 IRIS Evaluation, the United States Environmental Protection Agency recognized that an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers at sterilization operations using ethylene oxide, and there is sufficient evidence to establish a causal relationship between ethylene oxide exposure and breast cancer in women.
8. The 2016 IRIS Evaluation noted that as a mutagenic carcinogen, ethylene oxide causes cancer by damaging DNA in cells which is then duplicated when the cells divide. Exposure to ethylene oxide increases the cancer risk because DNA damage may take place with each and every exposure that is passed on to more cells, increasing the number of mutated cells, which eventually leads to cancer in some people.

9. Respondent's operations are conducted in a densely populated, residential, industrial, commercial and governmental area with more than 19,000 people living within 1 mile of Respondent's two buildings and many more working there. Within 1 mile of Respondent's buildings, there are homes, schools, parks, government buildings and businesses.
10. The United States Environmental Protection Agency identified 7 census tracts near Respondent's operations as having cancer risk scores greater than 1 in 10,000, i.e., an additional 1 incidence of cancer per 10,000 people.
11. The United States Environmental Protection Agency collected ambient air samples at 26 discrete locations near Respondent's operations and utilized that data to model short-term and long-term ambient concentrations of ethylene oxide in the area. The United States Environmental Protection Agency provided the ambient sampling data and the results of its modeling to the United States Department of Human Services' Agency for Toxic Substances and Disease Registry ("ATSDR") and requested that the ATSDR determine: "if modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?"
12. On August 21, 2018, the ATSDR issued a Public Health Consultation Letter to the USEPA in answer to the request set forth in paragraph 11. In that Consultation Letter, the ATSDR concluded, in part, that:

It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO [ethylene oxide] concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:

- 1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* (emphasis in original) for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated cancer risks *present a public health hazard to these populations* (emphasis in original).
13. The ATSDR used the highest [then-available] residential area and commercial area sampling results (2.1 micrograms per meter³ and 9.1 micrograms per meter³, respectively) to reach its conclusion.
14. Ambient air sampling was conducted by the United States Environmental Protection Agency and the Village of Willowbrook in November and December of 2018 and January and February of 2019. The ambient data collected in November and December of 2018 consistently found outdoor ambient levels of ethylene oxide in commercial and residential areas as high or higher than the levels used by ATSDR.
15. Regulations promulgated by the United States Environmental Protection Agency under the Clean Air Act's National Emission Standards for Hazardous Air Pollutants ("NESHAP") for emission of ethylene oxide from commercial sterilization operations, 40 C.F.R. Part 63, Subpart O, well before the recognition of ethylene oxide as a human carcinogen, only required control of emissions (99% reduction of inlet emissions into the control device) from the sterilization chamber evacuation systems and the aeration rooms and did not require control of emissions from sterilization chamber back vents or from other operations at the facility (i.e., movement of sterilized material from the sterilization chamber to the aeration room and from the aeration room into storage or out on trucks for customer deliveries). So far, the emission levels from those other operations have only been crudely estimated.

16. The testing required by the federal NESHAP regulations from the sterilization process only determines the efficiency of the control equipment.
17. In the Spring of 2018, Respondent applied for and obtained a permit authorizing the connection of its back vent emissions to its existing control devices. After completing the connection, Respondent performed testing of the emissions under observation by the Illinois Environmental Protection Agency and the United States Environmental Protection Agency and demonstrated 99% control was achieved.
18. Respondent's emissions are continuing to contribute to ambient levels of ethylene oxide in the atmosphere. This impact creates an imminent and substantial endangerment to public health or welfare.
19. The Illinois Environmental Protection Agency should seal such portions of Respondent's buildings as are necessary to prevent the commencement of any new sterilization cycles using ethylene oxide until measures are in place to prevent emissions of ethylene oxide that contribute to ambient levels of ethylene oxide which present a public health hazard to residents and off-site workers in the Willowbrook community.

THEREFORE, PURSUANT TO THE AUTHORITY VESTED IN THE DIRECTOR OF THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY BY SECTION 34(b) OF THE ILLINOIS ENVIRONMENTAL PROTECTION ACT, I HEREBY ORDER THAT THE FOLLOWING PORTIONS OF RESPONDENT'S BUILDINGS ARE SEALED FORTHWITH:

All storage containers of ethylene oxide.

Persons authorized, in writing, by the Director of the Illinois Environmental Protection Agency may access the sealed portion of these properties to conduct activities within the scope of their specified authorization.

SAID PROPERTY SHALL REMAIN SEALED UNTIL SUCH TIME AS THIS SEAL ORDER HAS BEEN RESCINDED BY THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY.

It is a Class A misdemeanor to break any seal or operate any sealed facility until the seal is removed according to law.

Signed:



John J. Kim, Acting Director

Environmental Protection Agency of
the State of Illinois

Date: 2-15-19

EXHIBIT 2

Letter Health Consultation

“Evaluation of Potential Health Impacts from Ethylene Oxide Emissions”

STERIGENICS INTERNATIONAL, INC.

WILLOWBROOK, ILLINOIS

AUGUST 21, 2018

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

You May Contact ATSDR TOLL FREE at
1-800-CDC-INFO

or

Visit our Home Page at: <http://www.atsdr.cdc.gov>

LETTER HEALTH CONSULTATION

“Evaluation of Potential Health Impacts from Ethylene Oxide Emissions”

STERIGENICS INTERNATIONAL, INC.

WILLOWBROOK, ILLINOIS

Prepared By:

U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations



DEPARTMENT OF HEALTH & HUMAN SERVICES
Agency for Toxic Substances and Disease Registry,
Region 5

Public Health Service
77 W. Jackson Blvd., Room 413
Chicago, IL 60604

July 26, 2018 *

Ed Nam
Director, Air and Radiation Division
United States Environmental Protection Agency, Region 5
77 W. Jackson Blvd., MS A-18J
Chicago, IL 60604

Dear Mr. Nam:

Since February 2018, ATSDR has met with U.S. EPA Region 5 Air and Radiation Division (ARD) staff regarding a change in the cancer risk basis for ethylene oxide (EtO) in the EPA Integrated Risk Information System (IRIS) and how that change affects general population risks estimated from EtO-emitting facilities in the draft 2014 National Air Toxics Assessment (NATA) update¹. In December 2016, IRIS changed EtO's adult-based inhalation unit risk from 0.0001 per microgram per cubic meter ($\mu\text{g}/\text{m}^3$) to 0.003 per $\mu\text{g}/\text{m}^3$, a 30-fold increase in cancer potency. It also changed EtO's cancer weight-of-evidence descriptor from "probably carcinogenic to humans" to "carcinogenic to humans". These changes could result in many census tracts having estimated cancer risks that are greater than 1 in 10,000 from EtO exposure identified through the draft NATA modeling of air emissions across the United States.

Specifically, ARD decided to evaluate the implications of this change at two sites, Sterigenics International, Inc. (referred to in the letter as "*Sterigenics*") in Willowbrook, IL and the Elé Corporation in McCook, IL. This letter addresses EtO emissions from the Sterigenics facility. In June 2018, after the monitoring results were received and reviewed, ARD requested that ATSDR review air measurements of EtO and modeling results of EtO emissions from Sterigenics and specifically answer the question: *If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?*

The air modeling data that U.S. EPA provided to ATSDR estimated potential short-term and long-term concentrations of EtO in ambient air surrounding the Sterigenics Corporation. Follow-up air monitoring data confirm the presence of elevated EtO at concentrations within a similar range to those estimated by the air modeling of Sterigenics emissions. Based on these measured and modeled concentrations and the proximity to residences and other commercial structures, cancer risks higher than 1 in 10,000 people may exist for some community members and workers exposed to airborne EtO in this community. If these measured and estimated concentrations represent chronic exposures

* Minor edits to the reference list have been incorporated into the final posted ATSDR Letter Health Consultation.

¹ The 2014 NATA is expected to be publicly available in the fall of 2018.

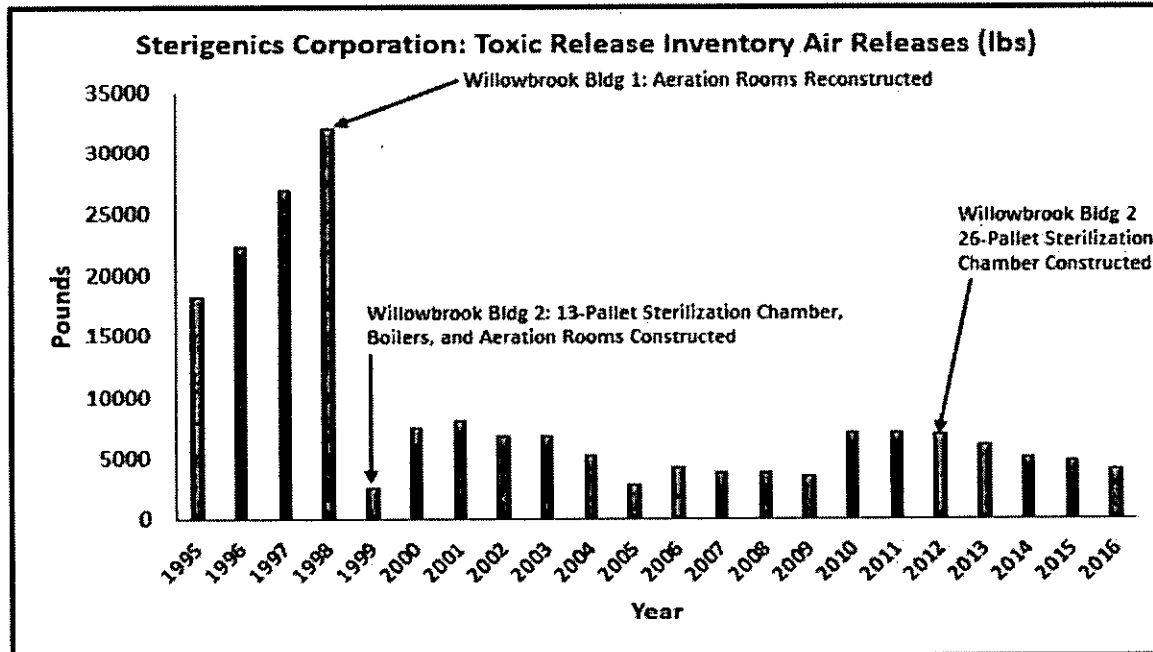
in the surrounding community (with higher exposures likely for workers of the facility), EtO emissions from the Sterigenics Corporation poses a public health hazard.

BACKGROUND

Sterigenics provides sterilization processes using gamma, ethylene oxide, Ebeam, and X-ray sterilization and operates 46 facilities in 13 countries (Sterigenics, 2018). The facility stores ethylene oxide that is sprayed into sealed chambers to sterilize medical equipment, pharmaceuticals, and food/spice products contained on 40" x 48" pallets. The sterilization chambers are contained in two buildings. Building 1 has fifteen chambers that can hold 1 to 13 pallets, while Building 2 has four sterilization chambers that can hold 13 to 26 pallets (Illinois EPA, 2017). Building 1 chambers were constructed in 1984, while Building 2 chambers were built in 1999 and 2012. Pollution control technology includes acid water scrubbers and dry bed reactors that convert the ethylene oxide to ethylene glycol after the sterilization process (Illinois EPA, 2015). Although back vents on the units have historically been uncontrolled, Sterigenics is currently in the process of installing pollution controls to control passive releases (ATSDR, 2018).

Figure 1 illustrates the total reported emissions in pounds per year (lbs/yr) of EtO from Sterigenics.

Figure 1. TRI Total Air Emissions Reported (in pounds), by Sterigenics Corporation for Ethylene Oxide, 1995-2016



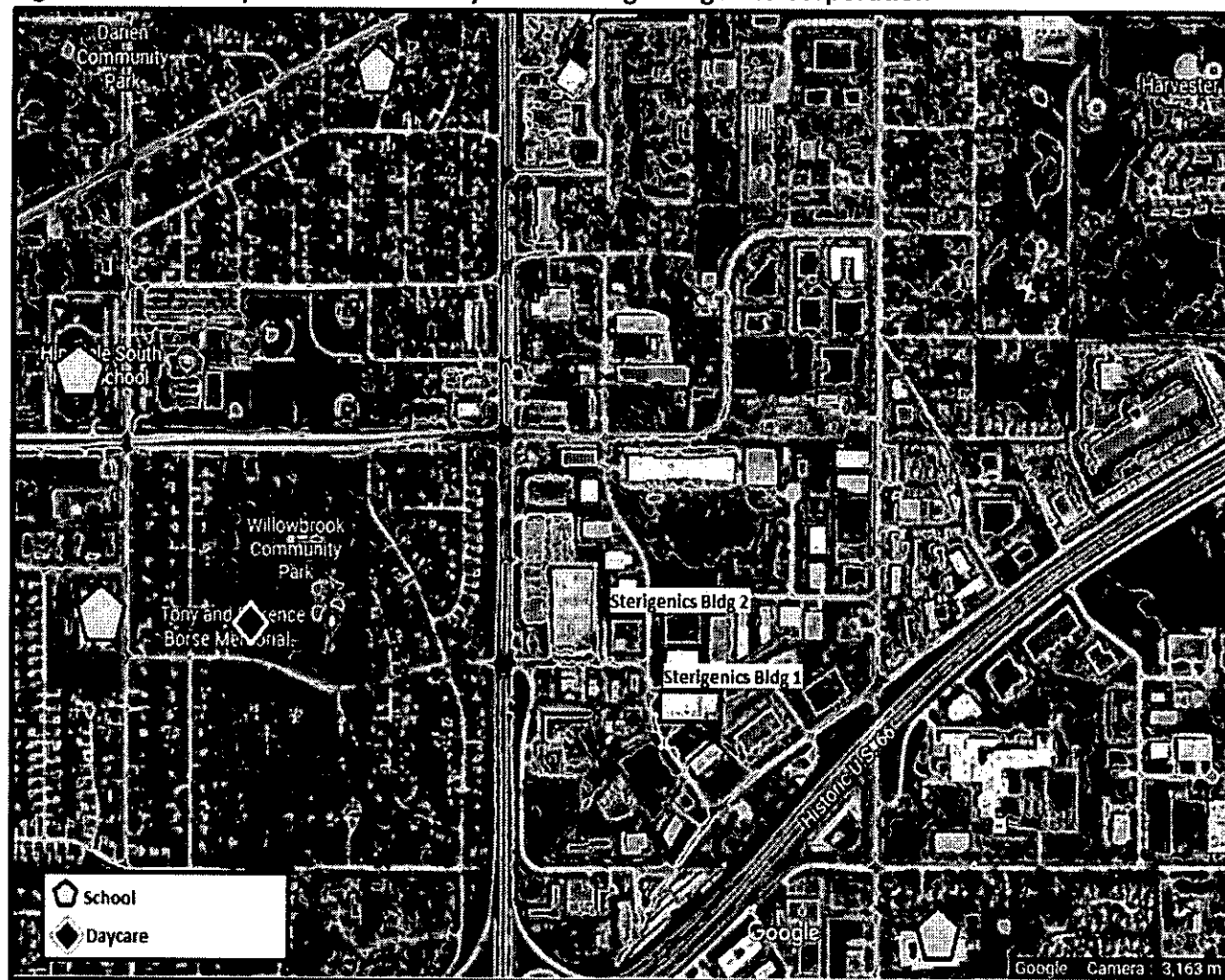
^aSource: Toxic Release Inventory (TRI): <https://www.epa.gov/enviro/tri-overview>

^bDates for facility constructed and upgrades were identified according to Illinois EPA (2017) DRAFT/PROPOSED Clean Air Act Permit Program (CAAPP) Permit

The emissions data show a substantial reduction in total air releases after 1998. No data are available before 1995 on ambient air releases, but the available data suggests that substantially higher ambient releases prior to 1995 were likely. The Building 1 sterilization chambers were constructed in 1984, therefore EtO has been emitted over the past 34 years from the Willowbrook facility.

Willowbrook, Illinois is a small suburb of Chicago with approximately 8,500 residents (U.S. Census, 2016). The Willowbrook industrial complex where Sterigenics is located is in a densely populated metropolitan area, with 19,271 people living within 1 mile of the facility boundary. There are four schools and one daycare facility within 1 mile of the facility. According to 2016 Census estimates, Willowbrook residents are predominately white (73.3%), non-Hispanic (66.6%), educated (97.7% graduate high school, and 48.9% graduated with a bachelor's degree or higher), and middle class (median household income was over \$67,000 per year). Approximately 18.5% of the population is identified as Asian, and 6.3% as black.

Figure 2. Aerial map of the community surrounding Sterigenics Corporation



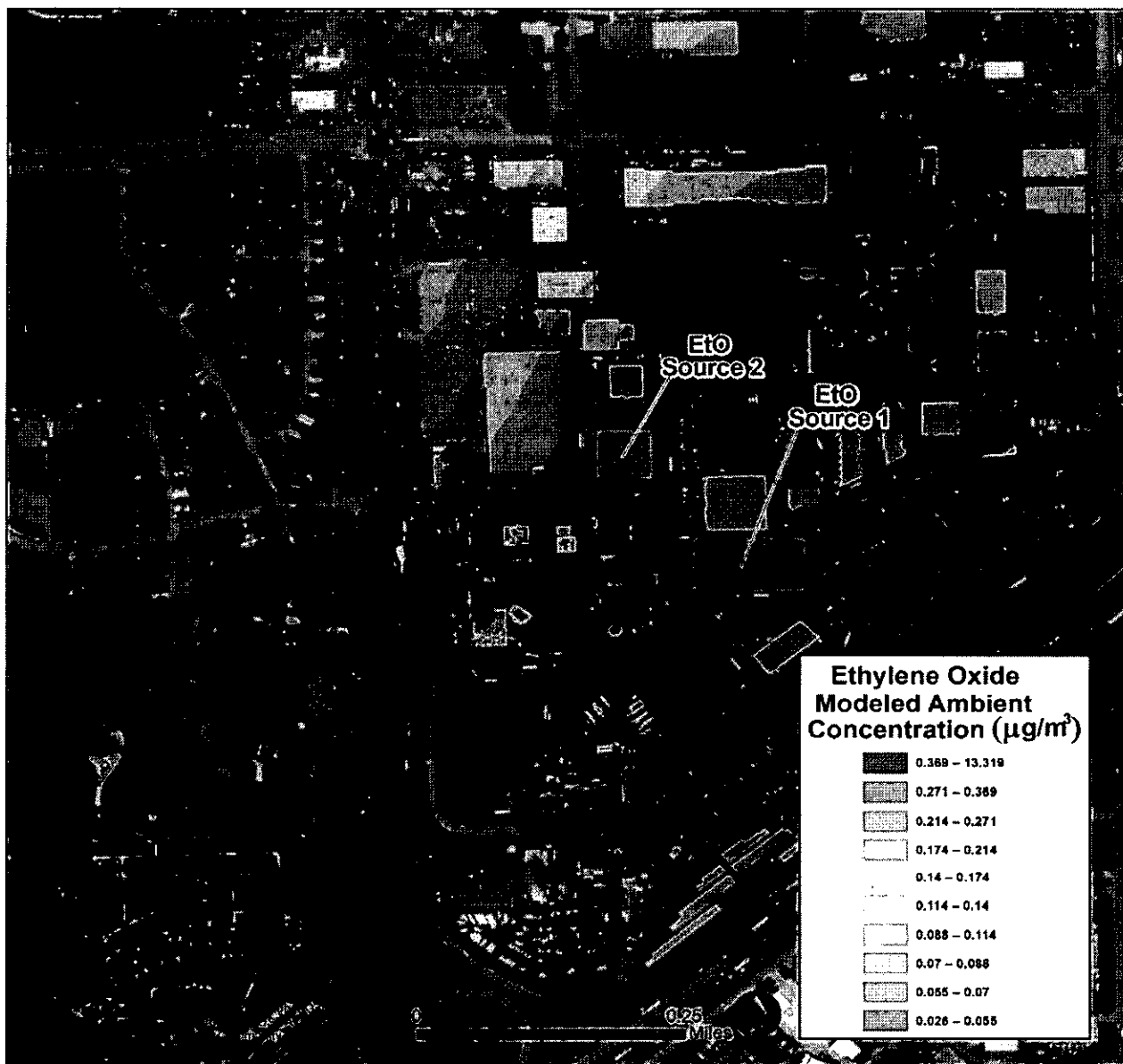
Source: Google Earth

ENVIRONMENTAL DATA

Air Modeling

U.S. EPA modeled short and long-term ambient EtO concentrations (AERMOD version 18081) to evaluate the potential impact of site emissions. These scenarios estimated a 5-year average to represent chronic exposures and maximum 1- and 8-hour averages to represent acute exposures at 882 community receptor points. An overlay of the modeling output is displayed in Figure 3, below. The statistical distributions of the modeled air concentrations are presented in Table 1.

Figure 3. AERMOD modeling output: 5-year average exposure estimates



Source: U.S. EPA Air and Radiation Division, Region 5

Note: Source 1 is Sterigenics Willowbrook Building 1, and Source 2 is Sterigenics Willowbrook Building 2

Table 1. Statistical distribution of EtO modeling*

Statistics	Modeled 1-hour ($\mu\text{g}/\text{m}^3$)	Modeled 8-hour ($\mu\text{g}/\text{m}^3$)	Modeled 5-year ($\mu\text{g}/\text{m}^3$)
Minimum	2.17	1.02	0.03
25th Percentile	4.62	2.26	0.09
50th Percentile	9.72	4.07	0.17
75th Percentile	18.88	7.29	0.31
90th Percentile	33.90	12.62	0.57
95th Percentile	45.22	18.83	0.91
99th Percentile	134.73	61.39	2.97
Maximum	249.77	123.89	13.32
Mean	15.75	6.72	0.32
Geometric Mean	10.13	4.41	0.18

*N= 882 modeled receptors

Air Measurements

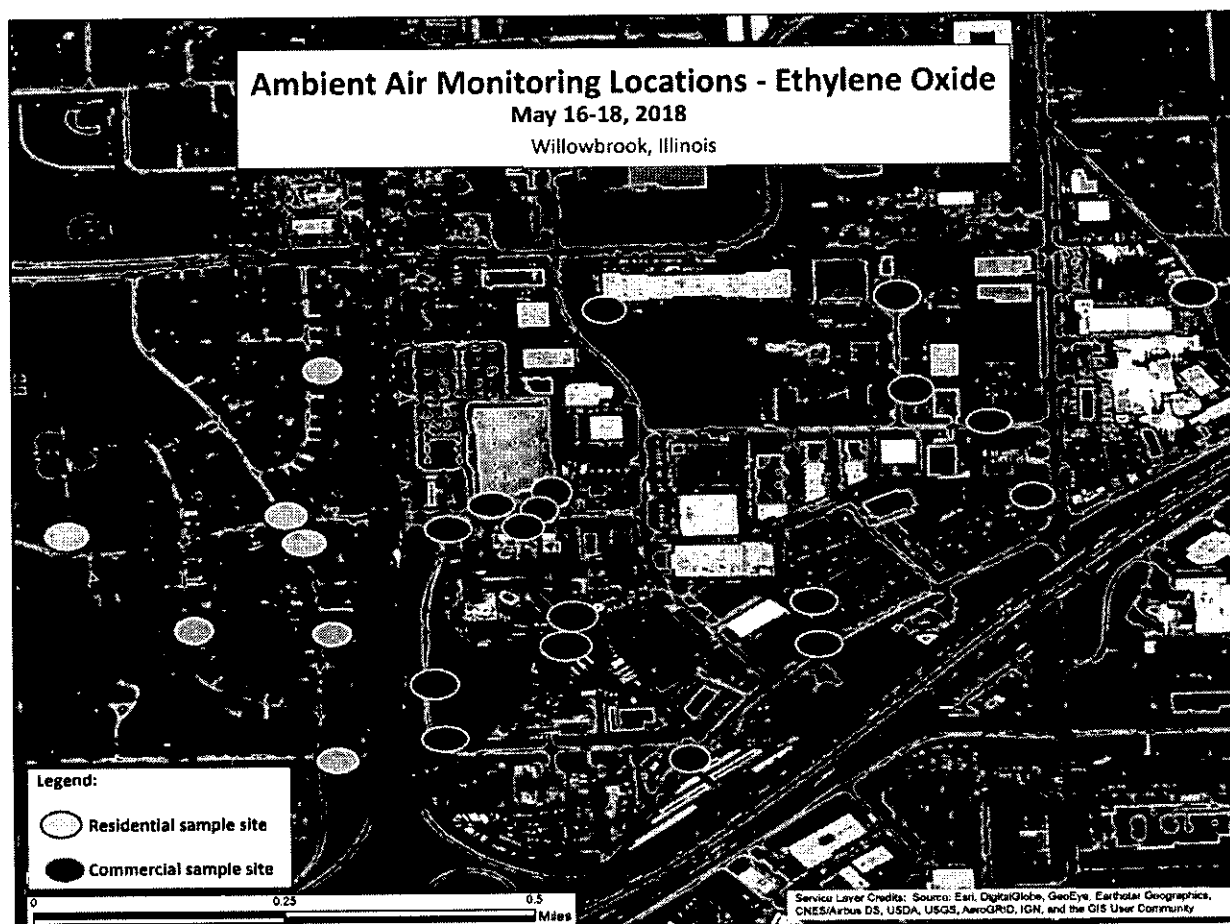
U.S. EPA collected 39 validated samples May 16th and May 17th, 2018. These samples were collected using SUMMA® canisters, and analyzed using U.S. EPA Compendium Method TO-15, Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air. A SUMMA® canister is an airtight, stainless-steel container with an inner surface that has been electro-polished and chemically deactivated. The laboratory is required to clean each canister and evacuate it to a high vacuum prior to shipping it to the sampling location. A canister can hold the vacuum for up to 30 days. The air being sampled is “drawn” into the canister by the high vacuum, thus eliminating the need for a pump. While opening the inlet orifice fills the canister in less than a minute, yielding an instantaneous “grab” sample, regulators can be added to the inlet orifice to draw the air into the canister over a designated period, ranging from 1 to 24-hours.

Of the 39 samples collected at 26 discrete locations (Figure 4), 18 were 12-hour samples, and 21 were grab samples (Table 2). Three of the 12-hour samples were collocated duplicates, and three of the grab samples were collocated duplicates. Grab samples generally had lower EtO concentrations than 12-hour averaged samples (U.S. EPA, 2018). However, all grab samples were collected between 10:20 am and 3:05 pm. ARD staff noted that higher EtO concentrations were measured overnight than during the day, and 12-hour samples were collected overnight in some locations. Since Sterigenics is a 24-hour operation, this may be due to calm meteorological conditions overnight with a higher potential for inversions. Given the elevated detections over a limited duration, additional long-term sampling is warranted to better characterize residential exposure to EtO.

Table 2. Statistical distribution of residential and commercial EtO air sampling*

Statistics	Grab samples ($\mu\text{g}/\text{m}^3$)	12-hour samples ($\mu\text{g}/\text{m}^3$)
Min	0.16	0.34
25th Percentile	0.24	0.69
50th Percentile	0.45	1.56
75th Percentile	1.34	4.39
90th Percentile	2.28	8.26
95th Percentile	4.27	8.44
99th Percentile	4.33	8.96
Max	4.34	9.09
Mean	1.07	3.02
Geo Mean	0.62	1.74

*N=21 grab samples, 18 12-hour samples

Figure 4. Ambient air samples near the Sterigenics facility, Willowbrook, IL

Source: U.S. EPA, Region 5

Figure 4, shows the location of discrete samples collected in the community. Given limited measured data presented in Table 2, ATSDR used the maximum 12-hour residential sample concentration and the maximum 12-hour commercial sample concentration to represent chronic upper bound residential ($2.1 \mu\text{g}/\text{m}^3$) and occupational ($9.1 \mu\text{g}/\text{m}^3$) exposures in the community. These concentrations represent maximums identified during a very temporally and spatially limited sampling campaign and actual average long-term exposures may be higher or lower.

HEALTH IMPLICATIONS

Overview for identifying contaminants of concern and evaluating risk

To evaluate EtO exposures near Sterigenics, ATSDR considered its own health-based comparison values as well as those published by other agencies. ATSDR uses comparison values for screening purposes to determine whether a pollutant should be evaluated further. A CV was identified for both an intermediate exposure duration (for non-cancer evaluation) as well as for a long-term (chronic) exposure duration (for which we considered both cancer and non-cancer health effects). In this evaluation, the air sampling results were compared to the ATSDR Cancer Risk Evaluation Guide (CREG) and environmental media evaluation guide (EMEG) and California EPA Reference Exposure Level (REL) for EtO.

- **ATSDR CREGs** are estimates of the concentrations of a carcinogen at which there is an elevated risk for one additional case of cancer in one million people exposed over a lifetime. ATSDR's CREG for EtO is calculated from the current U.S. EPA's adult-based inhalation unit risk value ($0.003 (\mu\text{g}/\text{m}^3)^{-1}$) and is based on U.S. EPA evaluations and assumptions about hypothetical cancer risks at low levels of exposure. ATSDR's CREG for EtO is $0.00021 \mu\text{g}/\text{m}^3$.
- **ATSDR inhalation minimal risk levels (MRL)/EMEGs** are estimates of the concentrations of pollutants calculated that anyone could be exposed to where health effects are unlikely, based on chronic, intermediate, and acute exposures (those occurring longer than 365 days, between 14-365 days, and 14 days of exposure or less, respectively). For EtO, ATSDR only has an intermediate EMEG of $160 \mu\text{g}/\text{m}^3$ (ATSDR, 1990).
- **California RELs** are concentrations that are unlikely to result in adverse non-cancer health effects. The chronic California REL for EtO is $30 \mu\text{g}/\text{m}^3$ (California EPA, 2008).

All 5-year modeled and 12-hour measured averages exceeded the ATSDR CREG. Only maximum modeled concentrations exceeded intermediate or chronic non-cancer screening values. The following sections evaluate chronic non-cancer and cancer risks further.

Ethylene oxide properties

Ethylene oxide is a highly flammable gas that is highly reactive with nucleophilic substances such as water, alcohols, halides, amines, and sulfhydryl compounds. It is used as an intermediate in the production of ethylene glycol and surfactants as well as a fumigant for sterilizing foods and heat-sensitive medical equipment.

EtO is highly reactive, readily absorbed, and easily distributed in the human body. The absolute odor threshold has been reported in several studies to be about 470 milligrams per cubic meter (mg/m^3)

(or 470,000 $\mu\text{g}/\text{m}^3$), with acute health effects possible in the range of the odor threshold (NRC, 2010). Chronic exposures can result somatic cell damage at much lower concentrations (California EPA, 2008). EtO is mutagenic and causes chromosome damage in many species, including humans. EtO exposure has widely been studied in scientific literature and its adverse health impacts are well understood. The carcinogenic effects of EtO have been documented in human and animal studies (U.S. EPA 2016).

Acute and intermediate exposure and health effects

Acute and intermediate effects have mostly been documented in hospital workers or in other occupational settings that include sterilizing chambers. Short-term exposure (minutes to weeks or months) above the odor threshold of 470 mg/m^3 (into the thousands of mg/m^3) include primarily neurological effects (headache, dizziness, nausea, lethargy, fatigue, muscle weakness, numbness, memory loss, incoordination, etc.), respiratory irritation (irritation of the nasal cavity, sinuses, coughing, shortness of breath, wheezing, and bronchial constriction and hyperreactivity), excessive thirst and dry mouth, and gastrointestinal effects (vomiting, diarrhea, stomach spasms, etc.). Some studies reported skin rashes with short-term exposures (NRC, 2010).

All studies with documented health effects summarized above had substantially higher EtO concentrations than what was observed in measured and modeled data in this assessment. ATSDR does not have an acute health-based comparison value but does have an intermediate-duration health-based comparison value of 160 $\mu\text{g}/\text{m}^3$. No measured data and only the maximum 1-hour modeled concentration of EtO exceeded this value and modeled and measured concentrations of EtO in this investigation were well below the odor threshold. Thus, it is unlikely that the non-cancer health effects noted above would occur in the general or off-site worker populations.

Chronic exposure and health effects

Cancer effects

The U.S. EPA IRIS released an "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" in December 2016. This evaluation summarizes the evidence that EtO is "carcinogenic to humans" through a mutagenic mode of action (MOA) and derives an inhalation unit risk value for EtO (U.S. EPA, 2016). Many studies have identified the genotoxic potential and mutagenic mode of action of EtO exposure via inhalation. There is clear evidence from multiple studies that EtO causes chromosomal aberrations, sister chromatic exchanges, and micronuclei in peripheral blood lymphocytes and bone marrow cells. Chromosomal aberrations and micronucleus frequency have been linked to increased risk of cancer in a number of large human studies (Jinot et al., 2017). Mice and rats exposed to EtO demonstrate cancers of the lymphohematopoietic system (cells involved in the production of lymphocytes and cells of blood, bone marrow, spleen, lymph nodes, and thymus), brain, lung, connective tissue, uterus, and mammary gland.

In humans, an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers in the EtO manufacturing and in sterilizing facilities (U.S. EPA, 2016). U.S. EPA identified six studies evaluating breast cancer in women, with the largest being a study from the National Institute of Occupational Safety and Health (NIOSH) of over 18,000 workers (45% male, 55% female) in 14 commercial sterilization plants. The NIOSH study reported statistically significant

exposure-response relationships for breast cancer incidence and mortality (Steenland et al., 2003 and Steenland et al., 2004). From assessing these studies, U.S. EPA (2016) determined that there is sufficient evidence of a causal relationship between EtO exposure and breast cancer in women.

U.S. EPA used the cancer incidence data from the NIOSH study, using individual exposure estimates for 17,530 workers from 13 plants, to calculate an inhalation unit risk value. A linear low-dose extrapolation of the lowest effective concentration (LEC; defined here as the lower 95% confidence limit on the EC_{01} , the estimated effective concentration associated with 1% extra risk) for lymphoid cancer was calculated as 2.9×10^{-3} per $\mu\text{g}/\text{m}^3$. Using the same approach, the lifetime unit risk for breast cancer was calculated as 8.1×10^{-4} per $\mu\text{g}/\text{m}^3$. Combining the risk for lymphoid and breast cancers in females U.S. EPA adopted an inhalation unit risk of 2.99×10^{-3} per $\mu\text{g}/\text{m}^3$ (rounded to 3.0×10^{-3} per $\mu\text{g}/\text{m}^3$). These adult-exposure only unit risk estimates were then rescaled to a lifetime, using age-dependent adjustment factors (ADAFs). ADAFs are used to incorporate the greater risk of early life exposure to chemicals that have a mutagenic MOA. When applying the ADAFs, EPA calculated an inhalation unit risk value over a 70-year lifetime of 5.0×10^{-3} per $\mu\text{g}/\text{m}^3$ (U.S. EPA, 2016). Cancer risk from measured and modeled EtO concentrations are estimated by multiplying the IUR by the EtO concentrations.

U.S. EPA Cancer Risk Estimates Reviewed by ATSDR

U.S. EPA Region 5 air modelers estimated cancer risk assuming a 70-year lifetime from measured and modeled data. Based on modeled EtO concentrations at over 882 specific locations around the Sterigenics facility, U.S. EPA used the 5-year average EtO concentrations to calculate lifetime cancer risks between 1.3×10^{-4} to 6.7×10^{-2} , with a geometric mean risk of 9.1×10^{-4} . Even though cancer risks are not generally calculated for short term exposures, the estimated cancer risks associated with the *measured* EtO air concentration (19 samples collected for 12 hours each) were similar (range: 7.9×10^{-4} to 4.5×10^{-2} , geometric mean: 7.7×10^{-3} ; Table 3). Note that these cancer risks were calculated using the lifetime ADAF-adjusted IUR of 5.0×10^{-3} per $\mu\text{g}/\text{m}^3$.

Table 3. Range of measured and modeled EtO concentrations: U.S. EPA Cancer Risk Estimates

Statistics	Modeled 5-year ($\mu\text{g}/\text{m}^3$)	Modeled cancer risk range	12-hour samples ($\mu\text{g}/\text{m}^3$)	Measured cancer risk range*
Minimum	0.03	1.3E-04	0.16	7.9E-04
Maximum	13.32	6.7E-02	4.34	4.5E-02
Mean	0.32	1.6E-03	1.04	1.4E-02
Geometric Mean	0.18	9.1E-04	0.61	7.7E-03

*Cancer risk was calculated to estimate what long term exposures to the 12-hour concentration could look like if sustained long term and does not represent actual exposures.

Cancer Risk Estimates Calculated by ATSDR

For ATSDR assessments, the reasonable maximum exposure (RME) scenario for residential exposure duration is 33 years over a lifetime of 78 years, so ATSDR calculated an IUR based on 33-year residential exposure using ADAFs. As mentioned previously, ATSDR's RME exposure point concentration (EPC) of $2.1 \mu\text{g}/\text{m}^3$ was used as a reasonable estimate of exposure for the most exposed individual in the community. This EPC is the maximum residential sample concentration of EtO in the May 2018 data collection period. Given these assumptions, the cancer risk for this residential sample

location is 6.4×10^{-3} —an additional lifetime risk of 6.4 cancers in a population of 1,000 residents who could be exposed to EtO emissions from Sterigenics. This cancer risk exceeds U.S. EPA's decision-making cancer risk range of 1.0×10^{-6} to 1.0×10^{-4} , and adds to the lifetime background cancer risk of an average American of 1 in 3 people (American Cancer Society, 2018).

Table 4. Site-specific ADAF calculations for residential exposure*

Age Range	ADAF	U.S. EPA unadjusted IUR	EPC ($\mu\text{g}/\text{m}^3$)	Duration Adjustment	Partial Risk
0 to <2 yrs	10	2.99×10^{-3}	2.1	2 years/78 years	1.6×10^{-3}
2 to <16 yrs	3	2.99×10^{-3}	2.1	14 years/78 years	3.4×10^{-3}
16 to 33 yrs	3	2.99×10^{-3}	2.1	17 years/78 years	1.4×10^{-3}
Lifetime Risk					6.4×10^{-3}

*Cancer risk was calculated to estimate what long term exposures to the 12-hour concentration could look like if sustained long term and does not represent actual exposures.

Likewise, ATSDR assumed the maximum commercial 12-hour sample concentration in commercial sample locations of $9.1 \mu\text{g}/\text{m}^3$ to represent RME occupational exposures to workers in nearby facilities. Note that workers at the Sterigenics facility would be covered under the Occupational Safety and Health Administration (OSHA) EtO standard (29 CFR 1910.1047). For the off-site worker scenario, ATSDR assumed an 8.5-hour workday, 250 days a year, for 25 years (ATSDR, 2016), yielding an exposure factor (EF) of 0.08.

$$EF_{\text{cancer, chronic}} = \frac{8.5 \frac{\text{hr}}{\text{d}} \times 5 \frac{\text{d}}{\text{wk}} \times 50 \frac{\text{wk}}{\text{yr}} \times 25 \text{ yr}}{24 \frac{\text{hr}}{\text{d}} \times 7 \frac{\text{d}}{\text{wk}} \times 52.14 \frac{\text{wk}}{\text{yr}} \times 78 \text{ yr}} = 0.08$$

Cancer risk for workers can be calculated by multiplying the long-term air concentration by the IUR, adjusting the duration of exposure as appropriate using the exposure factor calculation, above:

$$\text{Cancer risk} = \text{IUR} \times \text{EPC} (\mu\text{g}/\text{m}^3) \times \text{EF}$$

For the maximum commercial concentration of $9.1 \mu\text{g}/\text{m}^3$, this risk equation yields a lifetime occupational cancer risk of 2.1×10^{-3} , or an increased risk of cancer for 2.1 people in a population of 1,000 workers from chronic exposures to Sterigenics emissions:

$$\text{Cancer risk}_{\text{occupational}} = 0.00299 \times 9.1 \mu\text{g}/\text{m}^3 \times 0.08 = 2.1 \times 10^{-3}$$

While a more complete database from which to characterize exposure is preferable, we used U.S. EPA's limited data for the Sterigenics investigation and applied the standard ATSDR evaluation process. Note that in both ATSDR calculations, we made a very conservative assumption that a 12-hour sample represents long term exposure. We felt this assumption was warranted because the measured and modeled concentrations demonstrated consistency and provided support that this range of exposure is possible in the area surrounding Sterigenics.

Non-cancer effects

Workers exposed to ethylene oxide over a long-term duration experienced similar health effects to those exposed over shorter durations (California EPA, 2008). Workers exposed to levels of EtO at 8,500 $\mu\text{g}/\text{m}^3$ and higher over an average of 5-6.5 years demonstrated cognitive and motor impairment compared to unexposed controls. At lower levels of EtO exposure (145-300 $\mu\text{g}/\text{m}^3$), studies have shown evidence of hemoglobin adducts, DNA damage effects (i.e. sister chromatid exchanges), and hematological effects (i.e. increases in leukocytes and decreases in neutrophil counts; decreases in hematocrit and hemoglobin) (California EPA, 2008). No measured EtO concentrations from the residential or occupational sampling approached or exceeded effect levels in the long-term modeling estimates or the 12-hour samples being used as chronic exposure surrogates, therefore, non-cancer health effects are not expected. However, air sampling in this effort was extremely limited.

LIMITATIONS

ATSDR made several assumptions as part of this assessment that could lead to the over or underestimation of risk. Some limitations of this assessment include:

1. To calculate risks, ATSDR assumed that the concentrations measured during this assessment will continue, unchanged if no actions are taken, over 33 years for residents, and 25 years for workers.
2. ATSDR assumed that the very limited sampling investigation of 26 discrete locations over 2 days throughout the community represents typical exposure conditions from Sterigenics EtO emissions. Only one 12-hour residential sample was collected, and that sample was used to represent the RME residential chronic exposure estimate. EtO concentrations from grab samples at one other residential location were slightly higher than the 12-hour averaged sample collected at this property.
3. ATSDR assumed that the highest EtO concentration in the commercial area surrounding Sterigenics represents worst case off-site worker exposures. This is likely underestimating worker exposures for some employees in this area.
4. Due to a lack of long term sampling, the temporal trends of EtO emissions could not be evaluated. Fluctuations of seasons that affect temperatures, barometric pressure, wind speed and direction, and other potential factors that could influence the transport of EtO into the surrounding community were not assessed.

Despite these limitations, ATSDR acknowledges that the U.S. EPA modeling demonstrates similar concentration ranges to community air measurements. Thus, ATSDR believes the exposure estimates assumed in this assessment are reasonable. Historical emissions were higher before a substantial drop in 1999 with the construction of aeration rooms in Building 1. EtO cancer risks may have been substantially greater for the 14 years the facility operated before these emission controls were implemented, but historical risk cannot be evaluated with available emissions data.

Conclusions:

U.S. EPA asked ATSDR to answer the following question: *"If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?"* U.S. EPA provided modeled and measured data for ATSDR to evaluate and render a health opinion.

It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:


- 1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated risks *present a public health hazard to these populations*.
- 2) Measured and modeled ethylene oxide concentrations in ambient air indicate that non-cancer health effects are unlikely for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility.

Recommendations:

- 1) ATSDR recommends that Sterigenics take immediate action to reduce EtO emissions at this facility.
- 2) ATSDR recommends that U.S. EPA work with the Sterigenics facility to initiate long-term air monitoring as soon as possible to measure ambient air levels of EtO. Ongoing air monitoring can demonstrate the effectiveness of actions taken by the company to reduce emissions and subsequent exposures in the community.
- 3) ATSDR recommends that IDPH investigate whether there are elevated cancers in the population surrounding the Sterigenics facility that are consistent with those associated with chronic EtO exposures.

Please do not hesitate to contact ATSDR Region 5 to discuss this assessment further or to request further public health assistance.

Sincerely,



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EXHIBIT 3

Willowbrook, IL Ethylene Oxide Concentrations in Outdoor Air [ug/m³] - 24 Hour Samples

Sample Start Date	Willowbrook Village Hall	Willowbrook Village Hall 2	EPA Willowbrook Warehouse	EPA Willowbrook Warehouse 2	Gower Middle School	West Neighborhood	Water Tower	Willow Pond Park	Hinsdale South High School	Gower Elementary School
13-Nov-18	Invalid	-	2.37	-	-	-	-	-	-	-
16-Nov-18	0.824	-	1.81	1.81	-	-	-	-	-	-
19-Nov-18	6.11	6.31	6.62	-	0.155	0.125	0.246	0.105	0.253	0.164
23-Nov-18	0.284	-	0.180	Invalid	0.197	0.205	0.893	0.286	Invalid	0.202
25-Nov-18	4.10	-	Invalid	Invalid	0.360	0.261	Invalid	0.345	0.665	0.411
28-Nov-18	1.83	-	0.248	1.14	0.656	ND	0.699	0.455	0.376	0.474
1-Dec-18	1.68	1.90	0.456	-	0.140	0.804	ND	0.211	0.629	0.464
6-Dec-18	5.39	-	11.7	10.5	0.605	0.254	0.389	ND	0.486	ND
7-Dec-18	0.737	0.822	2.26	-	0.112	ND	0.273	0.403	ND	0.164
10-Dec-18	0.300	-	0.269	0.403	ND	0.213	0.248	ND	0.213	0.138
13-Dec-18	2.04	2.13	0.436	-	0.255	1.06	0.211	0.365	0.244	0.401
16-Dec-18	0.871	-	2.11	2.19	0.593	0.604	0.535	0.334	0.511	0.732
19-Dec-18	0.521	0.338	0.345	-	0.360	0.197	1.67	0.546	0.267	0.311
22-Dec-18	0.981	-	3.09	2.57	0.522	0.235	0.441	0.116	0.376	0.360
26-Dec-18	10.8	10.5	Invalid	-	ND	1.17	0.151	0.166	0.566	0.497
28-Dec-18	0.672	-	1.42	1.19	0.175	ND	Invalid	ND	0.264	0.133

Note: For quality assurance, EPA's monitoring plan calls for collocated samples to be collected for each sampling day at the Willowbrook Village Hall or the EPA Willowbrook Warehouse – the expected locations of maximum concentrations. Those data are reported in the table as Willowbrook Village Hall 2 and EPA Willowbrook Warehouse 2.

Note: On Nov 13 and 16, 2018, samples were only collected at Willowbrook Village Hall and the EPA Willowbrook Warehouse. Sampling began at the remaining locations Nov 19, 2018.

ND – non detect. Ethylene Oxide was either not present in the sample or was at a level below the level the method could detect.

Invalid -- the sample did not meet EPA's field, shipping, laboratory or other quality assurance criteria.

Trans -2- butene detected although concentration is too low to quantify .

As part of EPA's ongoing quality assurance efforts, the agency has updated a few results from November. These updates apply to a small number of lower concentration values; they do not change any of the higher values.